REMARKS

The Examiner has rejected claims 1-6, 11, and 14 under 35 U.S.C. § 102(e) as allegedly being anticipated by U.S. Patent No. 5,993,844 (the '844 patent). The Examiner indicates that the '844 patent anticipates claims 1-6, 11, and 14 because the '844 patent describes graft constructs that are endotoxin-free and, according to the Examiner, a graft construct that is "endotoxin-free" is within the ranges claimed in the present application. Applicants respectfully traverse the Examiner's rejection. Claims 1-6, 11, and 14 are not anticipated by the '844 patent.

Anticipation exists only if all the elements of the claimed invention are present in a product or process disclosed, expressly or inherently, in a single prior art reference. *Hazeltine Corp. v. RCA Corp.*, 468 U.S. 1228 (1984). The '844 patent describes a graft prosthesis from which non-collagenous material has been deliberately removed (see abstract and column 4, lines 1-3 of the '844 patent). The graft construct described in the '844 patent is rendered substantially free of glycoproteins, glycosaminoglycans, proteoglycans, and non-collagenous proteins (see abstract and column 3, lines 41-44). In fact, it is stated in the '844 patent that the method described therein removes non-collagenous components resulting in a matrix comprised substantially of collagen (see abstract and column 4, lines 1-3 of the '844 patent).

The graft constructs claimed in claims 1-6, 11, and 14 of the present application comprise a "collagen-based matrix structure." As stated on page 14, lines 1-2 of the present application, the matrices in accordance with the present invention contain one or more naturally occurring components including glycoproteins, glycosaminoglycans, and proteoglycans and/or growth factors. These components are naturally-occurring and not deliberately removed, as described in the '844 patent, so the presence of glycoproteins, glycosaminoglycans, and proteoglycans is not an exemplification as the Examiner suggests. The '844 patent describes a graft prosthesis from which these components have been deliberately removed. The Examiner suggests that Applicants have provided no proof that these components have been removed from the constructs described in the '844 patent. However, the '844 patent clearly indicates that these components are deliberately removed. Thus, the '844 patent cannot anticipate claims 1-6, 11,

and 14. Withdrawal of the rejection of claims 1-6, 11, and 14 under 35 U.S.C. § 102(e) as being anticipated by the '844 patent is respectfully requested.

Furthermore, Applicants have added claims 21-23 to the instant application. Claims 21-23 require that the claimed graft prosthesis comprises components selected from the group consisting of glycoproteins, glycosaminoglycans, and proteoglycans. Claims 21-23 cannot be anticipated by the '844 patent because the '844 patent describes a method for preparing a graft construct where non-collagenous components such glycoproteins, glycosaminoglycans, and proteoglycans are deliberately removed.

Moreover, with regard to the meaning of "EU/g," the Examiner previously contended that U.S. Provisional Application Serial No. 60/024,542 (the '542 application) did not contain support for the phrase "endotoxin units per gram," found in claim 3, because the '542 application did not set forth the meaning of "EU/g." According to the Examiner, this phrase could not be assumed to mean "endotoxin units per gram." However, the Examiner has now conceded, based on the evidence filed in Applicants' last response that "EU/g" is well-known in the art to mean "endotoxin units per gram" (see last paragraph on page 6 of the September 10, 2007 office action).

The '542 application, filed on August 23, 1996, recites less than "5 EU/g" on, for example, page 7, lines 16-17. Consequently, the Examiner should have removed the rejection of claim 3 over the '844 patent because there is support for the phrase "less than 5 endotoxin units per gram" in the '542 application. The effective filing date of claim 3 is August 23, 1996 which is prior to the filing date of the '844 patent. Accordingly, Applicants further request withdrawal of the rejection of claim 3 under 35 U.S.C. § 102(e) as being anticipated by the '844 patent because the '844 patent is not proper prior art to claim 3.

The Examiner has rejected claims 7-10 and 16-20 under 35 U.S.C. § 102(e) as allegedly being anticipated by the '844 patent or, in the alternative, as being obvious under 35 U.S.C. § 103(a) over the '844 patent. The arguments discussed above, in the first three paragraphs of this section of the response, apply with equal force to this rejection. Moreover, the

subject matter of claims 9, 10, and 16-20 is not disclosed or suggested by the '844 patent. The '844 patent provides no suggestion of cleaning the graft prosthesis prior to delamination (see claims 9, 10, and 16-20). Withdrawal of the rejection of claims 7-10 and 16-20 under 35 U.S.C. § 102(e) as being anticipated by the '844 patent, or under 35 U.S.C. § 103(a) as being obvious over the '844 patent is respectfully requested, based on both of the foregoing arguments.

Furthermore, Applicants have added claims 23-31 to the instant application. Claims 23-31 require that the claimed graft prosthesis comprises components selected from the group consisting of glycoproteins, glycosaminoglycans, and proteoglycans. Claims 23-31 cannot be anticipated by the '844 patent and cannot be obvious over the '844 patent because the '844 patent describes a method for preparing a graft construct where the method deliberately removes non-collagenous components such glycoproteins, glycosaminoglycans, and proteoglycans. In contrast, claims 23-31 require that the claimed graft prosthesis comprises components selected from the group consisting of glycoproteins, glycosaminoglycans, and proteoglycans as necessary components. Accordingly, claims 23-31 cannot be anticipated by the '844 patent and cannot be obvious over the '844 patent because the '844 patent teaches graft constructs where these components are deliberately removed.

The Examiner has rejected claims 12 and 13 under 35 U.S.C. § 103(a) as being obvious over the '844 patent. The Examiner has also rejected claim 15 under 35 U.S.C. § 103(a) as being obvious over the '844 patent in combination with Braun. The arguments discussed above, in the first three paragraphs of this section of the response, apply with equal force to this rejection in the context of obviousness. Withdrawal of the rejection of claims 12 and 13 under 35 U.S.C. § 103(a) as being obvious over the '844 patent is respectfully requested. Withdrawal of the rejection of claim 15 under 35 U.S.C. § 103(a) as being obvious over the '844 patent in combination with Braun is respectfully requested.

Furthermore, Applicants have added claims 32-34 to the instant application. Claims 32-34 require that the claimed graft prosthesis comprises components selected from the group consisting of glycoproteins, glycosaminoglycans, and proteoglycans. Claims 32-34 cannot

be obvious over the '844 patent because the '844 patent describes a method for preparing a graft construct where the method deliberately removes non-collagenous components such glycoproteins, glycosaminoglycans, and proteoglycans. In contrast, claims 32-34 require that the claimed graft prosthesis comprises components selected from the group consisting of glycoproteins, glycosaminoglycans, and proteoglycans as necessary components of the claimed graft prosthesis. Accordingly, claims 32-34 cannot be obvious over the '844 patent because the '844 patent teaches graft constructs where these components are deliberately removed.

The Examiner also pointed in the office action to Rule 41.202, in particular sections (a)(4) and (d), covering the requirement to make a showing of priority. A submission under Rule 41.202 is transmitted with this response. Although the Examiner indicates that Applicants are taking the exception of section "(2)" of 37 C.F.R. § 41.202(d), Applicants are not taking that exception (please see the submission under Rule 41.202 transmitted with this response).

CONCLUSION

The foregoing remarks are believed to fully respond to the Examiner's rejections. Applicants respectfully request issuance of an action indicating that the claims are allowable, and issuance of a declaration of interference.

Respectfully submitted,

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